and a second connection and between a first connector and a second connector." Office Action at page 2. The Office Action also states that "[c]laim 1 is indefinite for failing to particularly point out whether a first connector is a connecting tube of a first storage container." Office Action at page 2. The Office Action also states that "[c]laims 8-9 are indefinite for failing to particularly point out what does a cutoff device cut off." Office Action at page 2.

Applicants have amended claim 1 to include the structural relationship of the connections and connectors. Specifically, claim 1 has been amended to recite that "a first connection of the dialysis machine" and "a second connection of the dialysis machine". Claim 1 has also been amended to recite "a first connector of the first storage container configured to connect via a connection tube the first storage container to the first connection" and "a second connector of the second storage container configured to connect the second storage container to the second connection". In addition, Applicants have amended claim 8 to recite that the cutoff device cuts off a flow of at least one of a solution or a solution ingredient. As the second paragraph of 35 U.S.C. § 112 merely requires that the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity, see M.P.E.P. § 2173.02, it is respectfully submitted that claims 1 and 8 as amended satisfy this requirement. Furthermore, it is respectfully submitted that claims 2 to 7 and 9 satisfy this requirement by virtue of the amendments made herein to claims 1 and 8.

In view of the foregoing, it is respectfully submitted that claims 1 to 9 fully comply with the requirements of 35 U.S.C. § 112, and withdrawal of this rejection is therefore respectfully requested.

III. Rejection of Claims 1 to 4 and 6 to 9 Under 35 U.S.C. § 102(b)

Claims 1 to 4 and 6 to 9 were rejected under 35 U.S.C. 102(b) as anticipated by PCT Patent Publication No. WO96/25214 ("Kenley et al."). Applicants respectfully submit that Kenley et al. do not anticipate the present claims for the following reasons.

Claim 1 relates to a dialysis machine. Claim 1 recites that the dialysis machine includes a preparation device for preparing dialysis solutions. Claim 1

recites that the preparation device includes a detector device, a first connection of the dialysis machine, a second connection of the dialysis machine, and first and second interchangeable storage containers for solution ingredients. Claim 1 also recites that the preparation device includes a first connector of the first storage container configured to connect via a connection tube the first storage container to the first connection, and a second connector of the second storage container configured to connect the second storage container to the second connection. Claim 1 recites that at least one of the first connector or the connecting tube of the first storage container has an identifier detectable by the detector device.

Kenley et al. purport to relate to a machine for conducting dialysis of body fluids of a patient. The Office Action contends that "[Kenley et al.] teach[] a dialysis machine comprising a preparation device including a detector device, a first connection and a second connection in a form of cap (370) connected to first and second storage containers in a form of shell (380) of a bottle (270) wherein the first connector (370) has a touch bottom (362) in a form of bar codes showing the contents of the bottle and a touch button reader i.e. a detector for reading information coded in the touch button (362) and passing the information to a control module (25) i.e. analyzer unit capable of comparing the information from the touch button reader with stored memory of correct dialysate chemicals and activating alarm when the bottle (270) having improper chemical for the patient so that the incorrect bottle is removed (see figures 7A-10F; page 40, lines 14-23; page 42, line 18-46, line 8)." Office Action at pages 2 to 3. The Office Action also states that "[n]ote that multiple bottles (270) are placed in multiple applicators (260) in a chemical platform (250)." Office Action at p. 3.

It is respectfully submitted that Kenley et al. fail to anticipate claim 1 for at least the reason that Kenley et al. fail to disclose, or even suggest, all of the limitations of claim 1. For instance, it is respectfully submitted that Kenley et al. fail to disclose, or even suggest, a first connector of the first storage container configured to connect via a connection tube the first storage container to the first connection as recited in claim 1. The Specification describes at page 6, lines 18 to 20, that "[c]onnector 10 is arranged at the end of connecting tube 30, with the connecting tube being connected to a solution bag containing the required solution ingredients at the other end." The Specification also describes at page 7, lines 20 to

21, that "[t]he first solution bag has a connecting tube 30 and a connector 10 with a bar code 22." In contrast, Kenley et al. describe a bottle 270 having "a touch button 362 ... containing coded information as to the contents of the bottle 270 that is affixed to the neck of the bottle." Page 43, lines 3 to 4. As shown in Figures 10A and 10B, the neck of the bottle 270 that connects to the bottle 270 to the mounting member 354 above the applicator 260 is attached directly to the bottle, and does not include a tube as recited in amended claim 1.

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Kenley et al. do not disclose, or even suggest, at least a first connector of the first storage container configured to connect via a connection tube the first storage container to the first connection as recited in amended claim 1.

Additionally, to reject a claim under 35 U.S.C. § 102, the Examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. See, Scripps Clinic & Research Foundation v. Genentech, Inc., 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Still further, not only must each of the claim limitations be identically disclosed, an anticipatory reference must also enable a person having ordinary skill in the art to practice the claimed invention, namely the inventions of the rejected claims, as discussed above. See, Akzo, N.V. v. U.S.I.T.C., 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). In particular, it is respectfully submitted that, at least for the reasons discussed above, the reference relied upon would not enable a person having ordinary skill in the art to practice the inventions of the rejected claims, as discussed above. Also, to the extent that the Examiner is relying on the doctrine of inherency, the Examiner must provide a "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied art." See M.P.E.P. § 2112; emphasis in original; and see, Ex parte Levy, 17

U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic. Accordingly, the anticipation rejection as to the rejected claims must necessarily fail for the foregoing reasons.

In summary, it is respectfully submitted that Kenley et al. do not anticipate claim 1 as amended.

As for claims 2 to 4 and 6 to 9, which ultimately depend from amended claim 1 and therefore include all of the limitations of amended claim 1, it is respectfully submitted that Kenley et al. do not anticipate these dependent claims for at least the same reasons given above in support of the patentability of amended claim 1.

IV. Allowable Subject Matter

Applicants note with appreciation the indication of allowable subject matter contained in claim 5. In this regard, the Examiner will note that claim 5 has been amended herein to include all of the limitations of its respective base claim, i.e., claim 1, and any intervening claims, i.e., claim 4. It is therefore respectfully submitted that claim 5 as amended herein is in condition for immediate allowance.

V. Conclusion

Attached hereto is a marked-up version of the changes made to the claims by the current Amendment. The attached page is captioned "Version with Markings to Show Changes Made."

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

By:

Respectfully submitted,

KENYON & KENYON

Dated: <u>Jne 11, 2003</u>

Thomas C. Hughes Reg. No. 42,674

One Broadway New York, New York 10004 (212) 425-7200

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Version with Markings to Show Changes Made

IN THE CLAIMS:

Claims 1, 5 and 8 have been amended without prejudice as follows:

1. (Amended) A dialysis machine comprising:

a preparation device for preparing dialysis solutions, the preparation device including:

- a detector device[,];
- a first connection [and] of the dialysis machine;
- a second connection[,] of the dialysis machine:

first and second interchangeable storage containers for solution ingredients[, and];

a first connector of the first storage container configured to connect via a connection tube [for connecting] the first storage container to the first connection; and

a second connector of the second storage container configured to

connect [for connecting] the second storage container to the second connection,

wherein at least one of the first connector or the [a] connecting tube of the

first storage container has [having] an identifier detectable by the detector device.

5. (Amended) A [The] dialysis machine [as recited in claim 4] comprising: a preparation device for preparing dialysis solutions, the preparation device including a detector device, a first connection and a second connection, first and second interchangeable storage containers for solution ingredients, and a first connector for connecting the first storage container to the first connection and a second connector for connecting the second storage container to the second connection, the first connector or a connecting tube of the first storage container having a bar code detectable by the detector device, wherein the bar code is arranged on the first connector so that bars of the bar code run circumferentially around the connector.

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Version with Markings to Show Changes Made

8. (Amended) The dialysis machine as recited in claim 7, further comprising a signaling unit or cutoff device connectable to the analyzer unit, the cutoff device for cutting off a flow of at least one of a solution or a solution ingredient.